

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket Number: TLHR-0001WO/US  
In re the Application of: Peter John Meikle  
Serial No.: 10/517,899  
Filed: June 13, 2003  
Art Unit: unknown  
Examiner: unknown  
For: OLIGOSACCHARIDE BIOMARKERS FOR  
MUCOPOLYSACCHARIDOSES AND OTHER RELATED  
DISORDERS  
Attorney Docket No.: 124187.000012.US1 (TLHR-0001WO/US)

Mail Stop: PCT  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

EXPRESS MAIL NO. EV 312947758 US

DATE OF DEPOSIT: June 30, 2005


INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Herewith is Form PTO-1449 together with one copy of each document listed thereon.  
Please note also any item(s) designated below:

The information disclosure statement submitted herewith is being filed within  
three months of the filing date of the application or date of entry into the  
national stage of an international application or before the mailing date of a first  
  X   Office Action on the merits, which ever event occurs last 37 C.F.R. § 1.97(b).  
The fee set forth in 37 CFR 1.17(p)        is enclosed        may be charged to  
       Deposit Account Number 50-1752.  
Each document listed on enclosed Form PTO-1449 was first cited in any  
communication from a foreign patent office in a counterpart foreign application  
       not more than three months prior to the filing of this correspondence.

Respectfully submitted,

  
T. Ling Chwang  
Reg. No. 33,590

Date: June 30, 2005

Jackson Walker L.L.P.  
2435 N. Central Expressway, Suite 600  
Richardson, Texas 75080  
Phone: 972-744-2919  
Fax: 972-238-3319

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**Complete If Known**

Application Number	10/517,899
Filing Date	June 13, 2003
First Named Inventor	Peter John Meikle
Group Art Unit	
Examiner Name	

*(use as many sheets as necessary)*

Sheet	1	of	3 sheets
-------	---	----	----------

Attorney Docket Number | 124187.0012 US1 (TLHR-0001WO/US)

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )				
	4.	RU 2,196,988	01-19-2000	Dembure et al.,	Entire Patent	
	5.	WO 01/94941	12-13-2001	Millington et al.,	Entire Patent	
	6.	WO 03/048784	06-12-2003	Winchester et al,	Entire Patent	

Date Considered

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

3470921v.1

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3 sheets

**Complete if Known**

Application Number	10/517,899
Filing Date	June 13, 2003
First Named Inventor	Peter John Meikle
Group Art Unit	
Examiner Name	
Attorney Docket Number	124187.0012 US1 (TLHR-0001WO/US)

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	7.	BYERS S, Rozaklis T, Brumfield LK, Ranieri E, Hopwood JJ. Glycosaminoglycan accumulation and excretion in the mucopolysaccharidoses: characterization and basis of a diagnostic test for MPS. Mol Genet Metab 1998;65(4):282-90.	
	8.	DESAIRE H, Leary JA. Detection and Quantification of the Sulfated Disaccharides in Chondroitin Sulfate by Electrospray Tandem Mass Spectrometry. J Am Soc Mass Spectrom. 2000 Oct;11(10):916-20.	
	9.	ELLIOTT H, Hopwood JJ. Detection of the Sanfilippo D syndrome by the use of a radiolabeled monosaccharide sulfate as the substrate for the estimation of N-acetylglucosamine-6-sulfate sulfatase. Anal Biochem 1984;138(1):205-9.	
	10.	GERBER SA, Scott CR, Turecek F, Gelb MH. Direct Profiling of Multiple Eenzyme Activities in Human Cell Lysates by Affinity Chromatography/electrospray Ionization Mass Spectrometry: Application to Clinical Enzymology. Anal Chem. 2001 Apr 15;73(8):1651-7.	
	11.	HOPWOOD JJ, Elliott H. Urinary Excretion of Sulfated N-acetylhexosamines in Patients with Various Mucopolysaccharidoses. Biochem J 1985;229(3):579-86.	
	12.	HOPWOOD JJ, Harrison JR. High-resolution Electrophoresis of Urinary Glycosaminoglycans: an Improved Screening Test for the Mucopolysaccharidoses. Anal Biochem. 1982 Jan 1;119(1):120-7.	
	13.	HUA CT, Hopwood JJ, Carlsson SR, Harris RJ, Meikle PJ. Evaluation of the Lysosome-Associated Membrane Protein LAMP-2 as a Marker for Lysosomal Storage Disorders. Clin Chem 1998;44(10):2094-102.	
	14.	MEIKLE PJ, Brooks DA, Ravenscroft EM, Yan M, Williams RE, Jaunzems AE, et al. Diagnosis of Lysosomal Storage Disorders: Evaluation of Lysosome-Associated Membrane Protein LAMP-1 as a Diagnostic Marker. Clin Chem 1997;43(8 Pt 1):1325-35.	
	15.	NEUFELD EF, Meunzer J. The Mucopolysaccharidoses. In: Scriver CR, Beaudet AL, Sly WS, Valle D, editors. The Molecular Basis of Inherited Disease. New York: McGraw-Hill; 2001. p. 3421-52.	
	16.	PACKER NH, Lawson MA, Jardine DR, Redmond JW. A General Approach to Desalting Oligosaccharides Released from Glycoproteins. Glycoconj J. 1998 Aug;15(8):737-47.	

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3 sheets

**Complete if Known**

Application Number	10/517,899
Filing Date	June 13, 2003
First Named Inventor	Peter John Meikle
Group Art Unit	
Examiner Name	
Attorney Docket Number	124187.0012 US1 (TLHR-0001WO/US)

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	17.	PITT JJ, Gorman JJ. Oligosaccharide Characterization and Quantitation Using 1-phenyl-3-methyl-5-pyrazolone Derivatization and Matrix-Assisted Laser Desorption/ionization Time-of-Flight Mass Spectrometry. Anal Biochem. 1997 May 15;248(1):63-75. Related Articles, Links	
	18.	RAMSAY SL, Meikle PJ, Hopwood JJ. Determination of Monosaccharides and Disaccharides in Mucopolysaccharidoses Patients by Electrospray Ionisation Mass Spectrometry. Mol Genet Metab 2003;78(3):193-204.	
	19.	ROZAKLIS T, Ramsay SL, Whitfield PD, Ranieri E, Hopwood JJ, Meikle PJ. Determination of oligosaccharides in Pompe disease by electrospray ionization tandem mass spectrometry. Clin Chem. 2002 Jan;48(1):131-9.	
	20.	SCOTT HS, Litjens T, Nelson PV, Thompson PR, Brooks DA, Hopwood JJ, et al. Identification of mutations in the alpha-L-iduronidase gene (IDUA) that cause Hurler and Scheie syndromes. Am J Hum Genet 1993;53(5):973-86.	
	21.	SWEETMAN L. Newborn Screening by Tandem Mass Spectrometry: Gaining Experience. Clin Chem. 2001 Nov;47(11):1937-8.	
	22.	WHITFIELD P, Johnson AW, Dunn KA, Delauche AJ, Winchester BG, Franklin RJ. GM1-Gangliosidosis in a Cross-bred Dog Confirmed by Detection of GM1-ganglioside using Electrospray Ionisation-tandem Mass Spectrometry. Acta Neuropathol (Berl). 2000 Oct;100(4):409-14.	
	23.	PCT International Search Report, Australian Patent Office, August 29, 2003	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2.0 hours to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2